101172693 – VICT3R

Developing and implementing Virtual Control Groups to reduce animal use in Toxicology Research

WP9 – Qualification, certification of tools (CSV GLP – OECD 17) and regulatory interaction

D9.2. Computer System Validation

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Contents

Document History

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V0.2	10/09/2025	Version incorporating Formal Review comments
V0.3	02/10/2025	Version for Consortium Review
V1.0	17/10/2025	Final Version

Definitions

Participants of the VICT3R Consortium are referred to herein according to the following codes:

1. UNIVERSIDAD POMPEU FABRA (UPF)
2. SYNAPSE RESEARCH MANAGEMENT PARTNERS SL (SYNAPSE)
3. FRAUNHOFER GESELLSCHAFT ZUR FORDERUNG DER ANGEWANDTEN FORSCHUNG EV (ITEM)
4. GRITSYSTEMS AS (grit42)
5. TECHNISCHE UNIVERSITAT DORTMUND (TUDO)
6. PHUSE CUIDEACHTA FAOI THEORAINN RATHAIOCHTA (PHUSE)
7. MEDBIOINFORMATICS SOLUTIONS SL (MBIS)
8. BARCELONA SUPERCOMPUTING CENTER CENTRO NACIONAL DE SUPERCOMPUTACION (BSC CNS)
9. UNIVERSITAT KONSTANZ (UKON)
10. DECIPHEX LIMITED (Deciphex)
11. ORGANON SRL (Organon)
12. SYNCWORK AKTIENGESELLSCHAFT (Syncwork)
13. VRIJE UNIVERSITEIT BRUSSEL (VUB)
14. BAYER AKTIENGESELLSCHAFT (Bayer)
15. MERCK KOMMANDITGESELLSCHAFT AUF AKTIEN (MKDG)
16. AMGEN RESEARCH (MUNICH) GMBH (Amgen)
17. ASTRAZENECA UK LIMITED (AZ)
18. BASF SE (BASF SE)
19. BOEHRINGER INGELHEIM INTERNATIONALGMBH (BII)
20. BRISTOL-MYERS SQUIBB COMPANY CORP (BMS)
21. INCYTE BIOSCIENCES DISTRIBUTION B.V (Incyte BD)
22. INSTEM SCIENTIFIC LIMITED (Instem)
23. IPSEN INNOVATION SAS (IPSEN)
24. JANSSEN PHARMACEUTICA NV (Janssen)
25. NOVARTIS PHARMA AG (Novartis)
26. NOVO NORDISK A/S (Novo)
27. ORION OYJ (Orion)
28. PFIZER INC (Pfizer)
29. F. HOFFMANN-LA ROCHE AG (ROCHE)
30. SANOFI-AVENTIS DEUTSCHLAND GMBH (Sanofi)
31. TAKEDA PHARMACEUTICALS INTERNATIONAL AG (TPIZ)
32. UCB BIOPHARMA (UCB)
33. ABBVIE INC (AbbVie)
42. CAATEVENTS gGmbH (CAATevents)
43. GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED (GSK)
44. INSTITUT SERVIER DE MEDECINE TRANSLATIONNELLE (ISMT)
45. ZOETIS BELGIUM SA (ZOETIS)

Grant Agreement	The agreement signed between the beneficiaries and the IHI for the undertaking of the VICT3R project (101172693).
Project	The sum of all activities carried out in the framework of the Grant Agreement.
Consortium	The VICT3R Consortium, comprising the above-mentioned legal entities.
Consortium Agreement	Agreement concluded amongst VICT3R beneficiaries for the implementation of the Grant Agreement (GA). Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the GA.

Executive Summary

The VICT3R project is an Innovate Health Initiative (IHI)-funded public private partnership, bringing together industry partners, top academic institutions, and innovative small- and medium-sized enterprises, spanning from September 2024 to February 2028. The goal of the project is to reuse existing study data and artificial intelligence and statistics approaches to create and implement virtual control groups (VCG) for their use in future preclinical studies to reduce animal use in toxicology research.

VICT3R is a consortium-led and founded initiative with a broad variety of IT and industry partners. Therefore, a robust and flexible computerized validation strategy is essential for supporting business operations and achieving strategic goals.

This document describes the planned computer system validation activities and its validation deliverables together with a timeline for the implementation of the initial version of the VICT3R computerized system from a supplier perspective.

The VICT3R IT system infrastructure (i.e. network architecture, server & storage systems, cloud services, backup and disaster recovery) consisting of specified hardware and named software components (as mentioned in IHI deliverable “D9.1 - Inventory of algorithms and software tools”) will be referred during all below listed VICT3R validation activities. If applicable, relevant and important VICT3R IT-infrastructure components can be specified in detail within the “Description of Deliverable” and/or “Activity Explanation”.

Planned Activities / Timeline

Validation Step	Deliverable Description	Activity Explanation	Planned Due Date
Validation Framework	Specification of the VICT3R Validation Framework that acts as the guidance document for all VICT3R validation-related phases (like a standard operational procedure) and describes the required VICT3R validation documentation activities. It specifies how the document management of VICT3R validation has to be covered, and which approver roles act per defined VICT3R validation document.	Computer System Validation (CSV) experts, IT service providers, and defined stakeholders from VICT3R discuss and align on the VICT3R GxP validation strategy incl. the GxP documentation process within a couple of online sessions. Outcomes are tracked and structured as contents in the Validation Framework document, establishing a unified and harmonized validation workflow.	Mar 2025

Validation Step	Deliverable Description	Activity Explanation	Planned Due Date
GxP determination	Verification and Determination of the VICT3R GxP relevance based on an industry best practice questionnaire. All answers to questions from this questionnaire are assessed and dependent on their criticality, they lead to the final GxP determination for VICT3R.	Computer System Validation experts and defined stakeholders of VICT3R verify and answer the GxP questionnaire within up to three online sessions. The derived determination of GxP relevance for VICT3R is the key for the validation documentation efforts (according to regulatory requirements of OECD, FDA etc.), including test activities and system maintenance during the system lifecycle.	Mar 2025
Validation Preparation & Planning	Definition and alignment on the computer system validation strategy, including the list of deliverables and an estimated timetable for their delivery during the VICT3R validation phases. In addition, the validation plan contains a list of VICT3R roles and responsible members.	Computer System Validation experts define the required GxP validation deliverables of VICT3R, create a timeline for each validation phase, and align these plans with IT service providers and identified CSV stakeholders through a few online sessions. This ensures project transparency and provides a common foundation for all participants.	Mar 2025
Quality Plan	Creation of the VICT3R Quality Plan with expected quality objectives of the initial VICT3R software application, define an implementation strategy, a risk assessment, a project schedule and project documentation principles to be implemented for the initial VICT3R application.	Computer System Validation experts, IT service providers, and defined stakeholders of VICT3R specify, discuss and align on quality criteria within a couple of online sessions, being important to VICT3R and its system lifecycle. This activity is to ensure VICT3R will be reliable, safe, and compliant.	April 2025
Infrastructure description	Explanation of the expected VICT3R infrastructure environment & services including involved components and software packages.	IT service providers and Computer System Validation experts of VICT3R identify, list and verify the to be used hardware and software packages, and align on the provision of the VICT3R infrastructure within a couple of online sessions. This activity is for serving technical transparency about the VICT3R system.	April 2025

Validation Step	Deliverable Description	Activity Explanation	Planned Due Date
Development guideline	Definition of explicit VICT3R implementation rules and guidance for a standardized, high-quality software development process	Computer System Validation experts and IT Service Providers of VICT3R collect and identify a list of best practice rules and guidance for upcoming system implementation within a few online sessions. This activity should foster the high-quality approach during system development.	May 2025
Requirement Specification & Assessment	Specification of VICT3R user requirements and system-related requirements including a risk assessment to identify most critical VICT3R processes and data parts	In a couple of online sessions, CSV experts, IT providers, and VICT3R stakeholders define initial user and system requirements. Each requirement is assessed for functional, technical, or data criticality, and mitigation measures are specified for medium- or high-risk items. This process establishes the requirements for system implementation.	Jun 2025
Design & Implementation	Technical specification and design of the implemented VICT3R modules and their functional documentation	IT Service Providers of VICT3R collaborate to design and document the initial system architecture and define system modules for compliant data flow. As development progresses, functionalities are documented in parallel. Computer System Validation (CSV) experts review the design and documentation, suggesting improvements. The documentation is finalized jointly during online sessions to ensure high-quality system specifications.	Oct 2025
Informal Testing	Preparation and execution of informal VICT3R user & system tests about VICT3R process correctness and data integrity, as an optional activity. These tests also serve as preparation for the formal test and help to increase the quality of the formal execution.	IT Service Providers of VICT3R and Computer System Validation experts collaborate to establish an environment for VICT3R informal test activities by consortium users and initial system tests. This activity is to verify process accuracy before official validation tests will be initiated.	Nov 2025

Validation Step	Deliverable Description	Activity Explanation	Planned Due Date
Application installation in validation system	Installation of all implemented VICT3R modules in the validation system environment via Installation Qualification test cases to prove the correct installation procedure and the correct result.	VICT3R IT Service Provider set up the validation environment in a controlled way by running defined installation qualification scripts and document their results accurately. CSV experts review the outcome to ensure successful completion. Any installation deviation is addressed, assessed and probably mitigated by either script adjustment and re-installation or appropriate measures. This validation step is happening in a short period of time (in average less then a week).	Dec 2025
Initial system and user acceptance testing in validation system	Initial preparation and execution of VICT3R user acceptance test scripts incl. system test scripts in the validation environment	Computer System validation experts define and prepare required VICT3R user acceptance test (UAT) cases according to the risk assessment of the VICT3R requirements and its technical implementation. Identified Medium and high risks will be mitigated by one or more test case scenarios and executed by appropriate test users. Each user documents the execution results accurately. CSV experts review the outcome to ensure successful completion. Any test deviation is addressed, assessed and mitigated by either script adjustment and test repetition or adequate other measures. Finally, all UAT results are summarized in a validation test report. As UAT testing needs collaboration amongst different VICT3R caretaker and CSV experts, it will take up a couple of online sessions and individual one-on-one calls for several weeks.	Feb 2026
Documenta-tion & Training	Creation of the VICT3R administrator guide plus a VICT3R user manual, including training material for identified VICT3R user profiles	IT Service Providers of VICT3R will summarize their most relevant VICT3R administration activities for daily operations in an administrator guide. Computer System Validation	Apr 2026

Validation Step	Deliverable Description	Activity Explanation	Planned Due Date
		experts provide an overview of most important VICT3R system functionalities and available features, a description of the study and domain data plus a related procedure for VICT3R account registration. In addition, provision for help by a contact person or opening a service ticket e.g. for a bug fix is described in the VICT3R user manual. Beside this, some VICT3R training material will be provided for identified user roles, to ensure correct system handling. The to be created VICT3R documentation will be verified by quality assurance experts, IT service providers and CSV colleagues to ensure best quality. This activity delivers several outputs and needs collaboration amongst listed experts, either by some online meetings, one-on-one calls or individual reviews on demand.	
Preparation of validation summary report & Release for productive installation	Preparation of the VICT3R validation summary report, a completeness & correctness verification of defined stakeholders for the planned release of productive installation	Computer System validation experts summarize all validation activities from the validation plan against all validation deliverables and executed validation results (IQ,UAT), and verify their outcome for completeness and correctness in the VICT3R validation summary report. Any potentially identified deviation is listed together with their mitigation and its final outcome for high transparency. If all planned validation deliverables are successfully completed & approved, the productive installation qualification is released. The whole activity has an effort of potentially one to two weeks.	Apr 2026
Productive Installation,	Installation & Rollout of the implemented VICT3R application in	VICT3R IT Service Providers set up the validated productive VICT3R	May 2026

Validation Step	Deliverable Description	Activity Explanation	Planned Due Date
Extension of Validation Summary Report, incl. Approval & Initial Golive	the productive system environment. Analogous to the validation environment, the installation of all implemented VICT3R modules in the production system environment via Installation Qualification test cases is performed to prove the correct installation procedure and the correct result.	environment in a controlled way by executing defined installation qualification scripts and document their results accurately. CSV experts review the outcome of the installation in the productive environment and extend the validation summary report by the results accordingly. Afterwards, the final report verification and approval by Quality Assurance experts and identified CSV stakeholders is initiated. After approval of the validation summary report an individual user login demonstrates all system functionalities are in place for productive VICT3R golive. The duration of this activity is lasting a few days only (e.g. often executed on a weekend or during public holidays).	